Insect biotechnology in the United States and the EU

Talking Points

GE Insects

- The olive fly is responsible for considerable damage to olive production in Europe, especially this last year. Is the EU considering the use of GE insects to control this pest in the future? Are there any GE insects (e.g., Mosquitos, Olive flies, or Medflies) currently under review in the EU, either for approval or caged trials?

[Only if asked:]

GE Mosquito:

- FDA released a final environmental assessment (EA) on the potential environmental impacts of conducting a field trial of Oxitec's GE *Aedes aegypti* mosquito in Key Haven, FL and a final finding of no significant impact (FONSI) agreeing with the EA's conclusion that the proposed field trial will not have significant impacts on the environment.
- No trial releases of this GE mosquito (intended to control mosquitos that carry human disease causing agents such as Zika and dengue) have yet occurred in the United States.

GE Pink Bollworm:

- In 2006, APHIS BRS completed an environmental assessment and issued a permit for field trials of pink bollworm genetically engineered to express green fluorescence as a marker.
- Since then, field trials have occurred under APHIS BRS permits using pink bollworms genetically engineered to express red or green fluorescence proteins.

GE Diamondback Moth:

- USDA/APHIS published a draft EA for public comment for the Oxitec Diamondback Moth in August 2014. Following APHIS' analysis of the public comments received on the EA, APHIS revised its EA and prepared a Finding of No Significant Impact (FONSI). These documents, the final EA and FONSI, were posted on APHIS' web page in November 2014. Due to a clerical issue, the EA and FONSI have been withdrawn, Cornell University has resubmitted an application and APHIS BRS is currently reviewing the new permit application.
- Only caged field releases of GE diamondback moths have occurred.

Background

Oxitec, a British company now wholly owned by an American company, Intrexon, has developed GE insects for population suppression of the same species in the wild based on a genetic sterile insect technique that is currently undergoing regulatory review in the United States (and other countries). The goal for this technology is to reduce the local target insect population by the release of conditionally lethal GE males of the same species that mate with wild females. The GE males do produce sperm which can fertilize the female's eggs; however, the resulting hemizygous offspring will inherit the self-limiting gene from the homozygous GE

male parent and will die before reaching adulthood. In some implementations (Oxitec GE mosquito), offspring of both sexes will die before reaching adulthood, whereas in other implementations (e.g. diamondback moth) only female offspring will die. The same technology is used to control insects for both human health and agricultural purposes.

Regulation of GE Insects in the United States: The characteristics or intended use of the GE insect determines which agency(ies) has jurisdiction for its regulation. APHIS-BRS regulations govern GE insects that are plant pests (i.e. harm or damage plants or plant products). According to FDA's draft Guidance For Industry #236, EPA will regulate products intended to reduce the population of mosquitoes and FDA will regulate products intended to reduce the virus/pathogen load within a mosquito and also products intended to prevent mosquito-borne disease in humans or animals. FDA's Center for Veterinary Medicine (FDA-CVM) has said it will regulate GE insects that are not regulated by another U.S. government agency, such as those that are not regulated by APHIS-BRS or EPA under their regulations. [also see Briefing Paper on "Modernizing the U.S. regulatory system for biotechnology products".]

For insect plant pests, such as strains of Oxitec's GE diamondback moth (a pest of cruciferous crops, such as cabbage) and Oxitec's GE pink bollworm, the Animal and Plant Health Inspection Service (APHIS), pursuant to the Plant Protection Act of 2000, regulates genetically engineered plant pests under its regulations at 7 CFR part 340. In response to a permit application from Cornell University for field release of an Oxitec strain of GE diamondback moth, APHIS BRS posted to its web site its final environmental assessment and FONSI for this GE moth in November 2014. However, while APHIS reached a finding of no significant impact (FONSI) in connection with this permitted release and posted that FONSI on their Web site, the public was not notified via a second notice in the Federal Register. Therefore, APHIS/BRS withdrew the EA and FONSI associated with the notice (notice of withdrawal was posted November 2016). At this point, only caged field releases of GE diamond back moths have occurred. Cornell University withdrew its permit application in April 2016 (see above) and reapplied shortly thereafter. APHIS BRS is currently reviewing the new permit application for field release of the Oxitec strain of GE diamondback moth.

In 2006, APHIS BRS completed an environmental assessment and issued a permit to an APHIS researcher for field trials using an Oxitec strain of pink bollworm genetically engineered to express green fluorescence as a marker. Between 2006 and 2016, the permittee has conducted field trials under APHIS BRS permits using pink bollworms genetically engineered to express red or green fluorescence proteins as a marker.

In addition to the diamondback moth and pink bollworm, Oxitec has produced a number of GE insects for the control of insect plant pests, including the Olive Fly, Medfly (an Oxitec GE Medfly is approved for field trials in Brazil), and Mexfly. [*NB: The Oxitec GE olive fly that is in development is targeted at the European olive industry (e.g., Spain).*]

GE mosquito: FDA/CVM is reviewing information on the Oxitec mosquito in consultation with other U.S. Government experts (the regulation of this GE mosquito is expected to move to EPA as described in FDA's draft Guidance for Industry #236). In March 2016, FDA released for public comment Oxitec's draft EA on the potential environmental impacts of conducting a field

trial on their GE *Aedes aegypti* mosquito in Key Haven, FL and a preliminary FONSI. Before any trial releases of this GE mosquito (intended to control mosquitos that carry human disease causing agents such as Zika and dengue). On August 5, 2016, FDA released a final EA and FONSI agreeing with the EA's conclusion that the proposed field trial will not have significant impacts on the environment.

In November 2016, there were non-binding resolutions on two local Florida ballots regarding the release of GE mosquitos. Voters in Monroe county Florida approved releasing of the GE mosquitos in their county, while voters in Key Haven rejected the resolution. Officials from the mosquito control board for the Florida Keys said they intended to honor the will of the people. However, it's not clear how the board will proceed given the split vote. No releases of GE mosquitos have yet occurred in the United States.

In April 2016, this GE mosquito received a special temporary registration from the National Health Surveillance Agency of Brazil (ANVISA). In 2014 the National Technical Commission of Biosecurity (CTNBio) found the Oxitec mosquito safe to use in Brazil.

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